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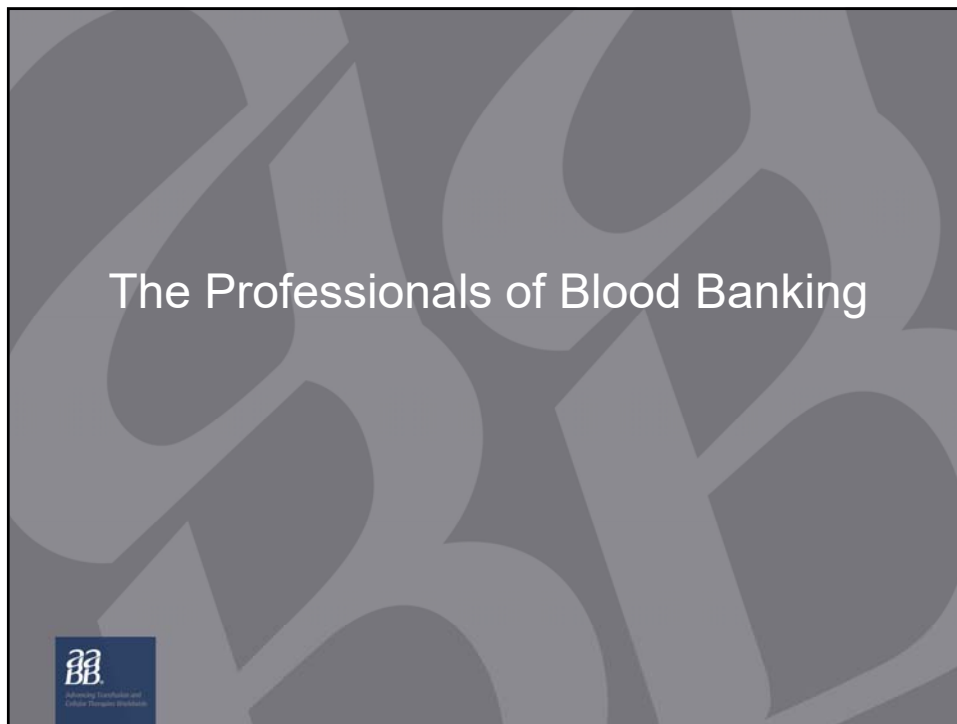
Learning Objectives

After participating in this program you should be able to....

- Define and discuss medical professionals who collect, oversee or manufacture blood components.
- Describe the role of the FDA, CLIA and other regulatory bodies in blood manufacturing.
- Explain the operational logistics required in determining appropriate blood inventory for a geographic region and the process of meeting daily, weekly, and monthly collection goals.




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Medical Staff

- **Education**
 - Usually a pathologist with residency in transfusion medicine
 - Can be a MD or DO
- **Responsibilities**
 - Consult with blood bank staff
 - Consult with patient's physicians
 - Review adverse reactions
 - Teach
 - Approve SOPs

The slide has a white background with a black border. The title "Medical Staff" is in a blue, sans-serif font. Below it is a bulleted list with two main categories: "Education" and "Responsibilities", each followed by a list of specific tasks or roles. In the bottom-left corner, there is a small blue square logo with the white letters "AABB" and the text "Advancing Transfusion and Cellular Therapies Worldwide" below it.

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Clinical Laboratory Technologist

- Education Requirements
 - 4 year BS degree
 - HHW route
- Responsibilities
 - Perform testing
 - Crossmatch
 - Antibody screens and identifications
 - With experience may perform tests normally delegated to SBB



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Clinical Laboratory Technician

- Education Requirements
 - Associates degree
- Responsibilities
 - Perform routine laboratory testing



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Phlebotomists

- **Education Requirements**
 - Certification desirable but many are trained on the job
- **Responsibilities**
 - Screen donors
 - Take blood samples
 - Draw donors
 - Label
 - Provide excellence in donor care and customer service



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Specialist in Blood Banking

- **Education Requirements**
 - BS degree with a major in biology, microbiology or another biological or physical science
 - Certification as a medical technologist
 - Attend SBB school and pass exam
 - Study and pass exam
- **Responsibilities**
 - Perform specialized testing
 - Work with difficult patient samples



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Nursing Staff

- Education Requirements
 - RN
 - LPN
- Responsibilities
 - Perform specialized apheresis procedures
 - Personalized medicine
 - Granulocyte harvest



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Manufacturing and Distribution Technicians

- Education
 - High School diploma or equivalent
- Responsibilities
 - Process whole blood into components
 - Leukoreduction
 - Filling orders for hospitals and other customers



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Drivers

- Education
 - May need CDL
- Responsibilities
 - Deliver blood and blood products
 - Drive mobile buses and trucks



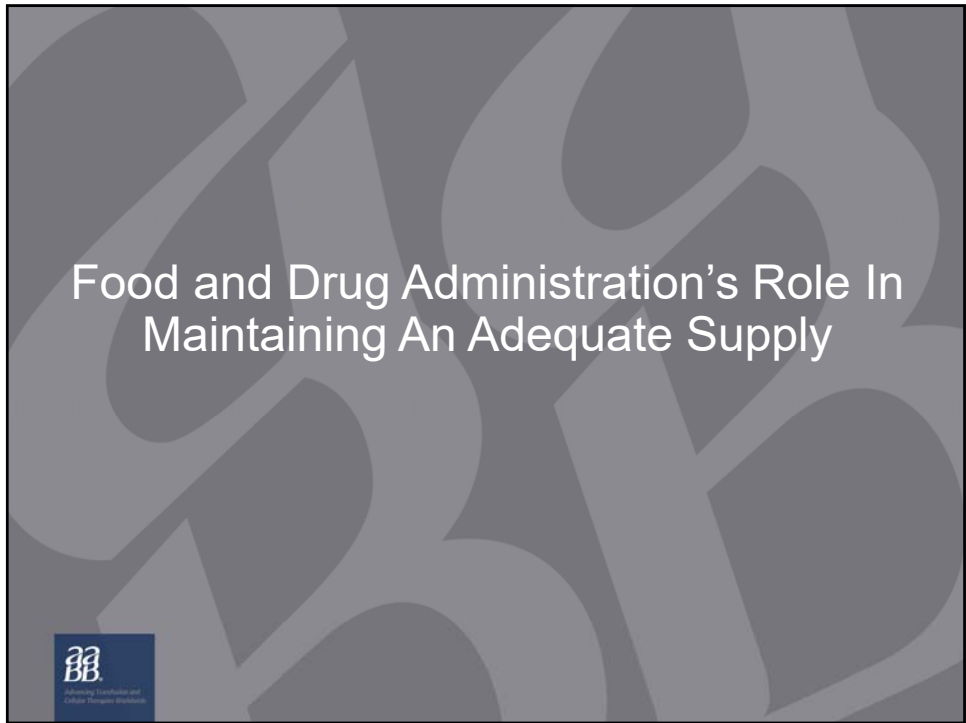
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Others Who Work in Transfusion Medicine

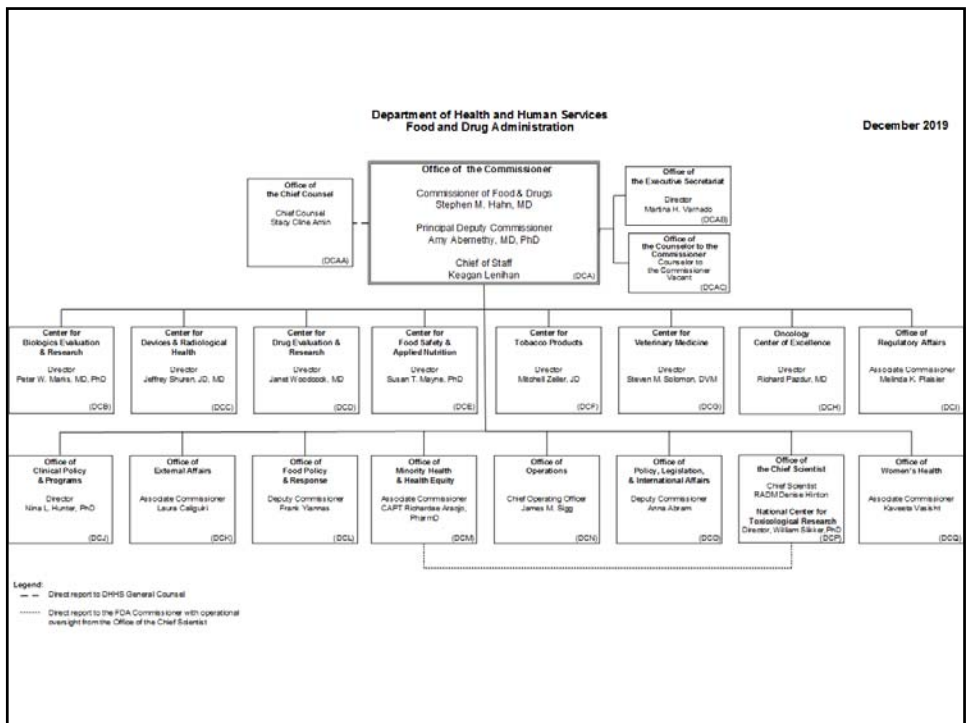
- Recruiters
 - Field
 - Telerecruiters
- Marketing professionals
- PR professionals
- Volunteers



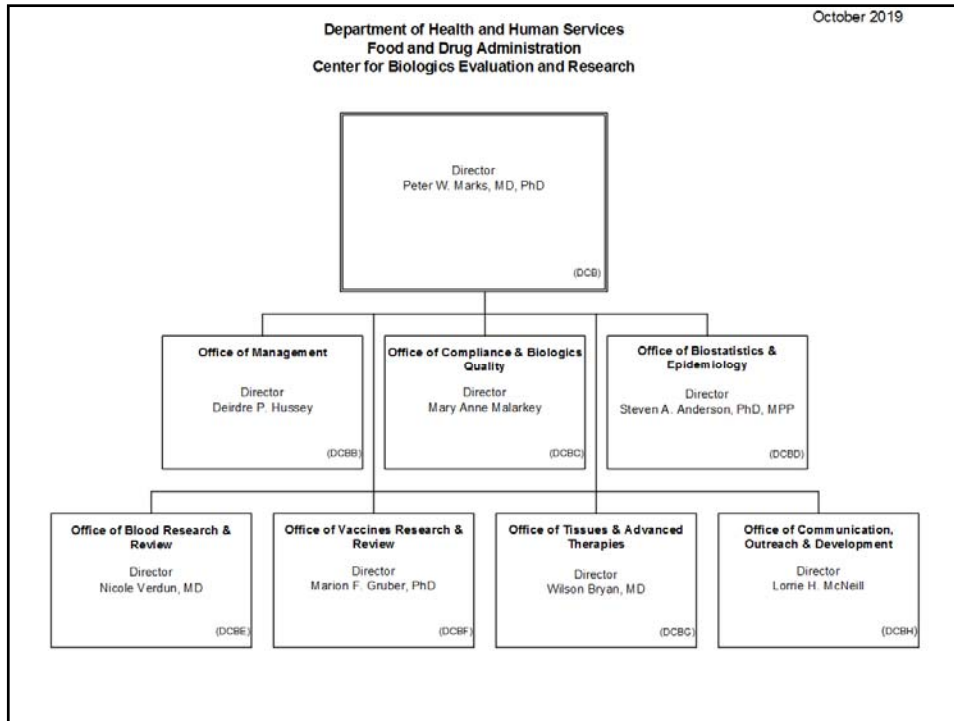
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Mission Of CBER

The mission of the Center for Biologics Evaluation and Research (CBER) is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Through our mission, we also seek to protect the public against the threats of emerging infectious diseases and bioterrorism.



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History of the Regulations

Year	Event
1901	13 children contract tetanus from a vaccine made from "Jim", an infected horse resulting in the Biologics Control Act being issued in 1902
1906	The Jungle is published resulting in the Pure Food and Drug Act
1912	Public Health Service Act
1937	Elixir sulfanilamide incident. Sulfanilamide is made in liquid form using a solvent similar to antifreeze. Due to poor recordkeeping 100 children die.
1958	Thalidomide causes numerous and horrible birth defects in pregnant women who took the drug as a mild sedative. Drug had been inadequately tested for safety.
1938	Food, Drug & Cosmetic Act published – required testing for safety
1944	Public Health Services Act – licensure for biologic products
1963	21 CFR 210, 211 published – Drug GMPs
1972	Regulation of Blood Banks transferred to FDA
1975	Blood classified as both drug and biologic
1990s	Increased scrutiny of Blood Banks by FDA
1993	First Consent Decree issued to a Blood Bank
1994	FDA requires 510 (k) clearance of Blood Establishment Computer Systems (BECS)
1995	FDA issues Quality Assurance Guidelines for Blood Establishments



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Purpose Of The FDA

- Rule making
- Licensing
- Inspection



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Rule Making

- 21 CFR
 - Laws, state minimal requirements
 - Part 200
 - Good manufacturing practice, drugs
 - Part 600
 - Good manufacturing practice, biologics
 - Part 800
 - Quality Systems Regulations
- Guidance Documents



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Regulation vs Accreditation

- | | |
|---|---|
| <ul style="list-style-type: none">• Regulation<ul style="list-style-type: none">– Laws– Must follow• The Food and Drug Administration (FDA) is an example of a regulator. | <ul style="list-style-type: none">• Accreditation<ul style="list-style-type: none">– Voluntary– Elect to follow• AABB and FACT are examples of accrediting organizations. |
|---|---|



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Licensing

- BLA
 - Establishment
 - Products
- Required for interstate commerce



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Inspections

- At least biannual
- Types of inspections
 - Routine
 - Follow-up
 - Complaint
 - Pre-licensure



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Areas the FDA Inspects

- Organization and personnel
- Buildings and facilities
- Equipment
- Production and process controls
- Holding and distribution
- Finished product control/labeling
- Laboratory controls
- Records and reports
- Facilities
- Environmental control
- Equipment
- Supplies/reagents
- Processing/process controls
- Storage
- Receipt, predistribution and distribution
- Donor eligibility



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Systems Based Approach

- Quality Assurance
- Donor Eligibility
- Product Testing
- Product Collection, Component Preparation and Labeling
- Quarantine/Storage/Disposition



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5 Layers of Safety

- Donor Screening
- Donor Deferral
- Product Testing
- Quarantine
- Monitoring and Investigating Problems



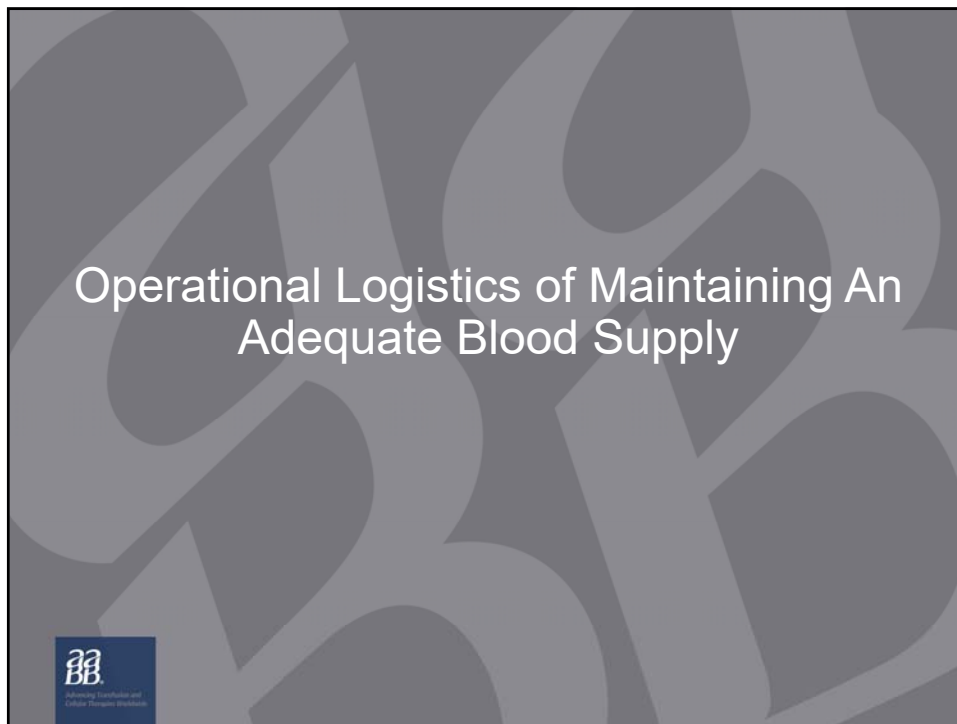
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Inspectional Outcomes for Noncompliance

- 483
- Warning letters
- Consent decree
- Legal action



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Recruitment Strategies

- Mobile Apps
- Streaming Media
- Press Releases
- Video
- Retargeting



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Recruitment Strategies

- Live Chat
- Blogging
- Email
- Google Ads
- Display Ads
- Podcasts



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Recruitment Strategies

- Social Media
- App Creation
- User generated content
- Texting



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Understanding Donor Demographics

- Where they live
- Generational factors
- Education
- Work patterns
- Where they shop



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Factors To Consider When Setting Up a Blood Drive

- Size of the organization
- Demographics of employees
- Proximity to fixed site
- Distance from processing facility
- Availability of staff
- Availability of room or will mobile bus be needed
- Champion?



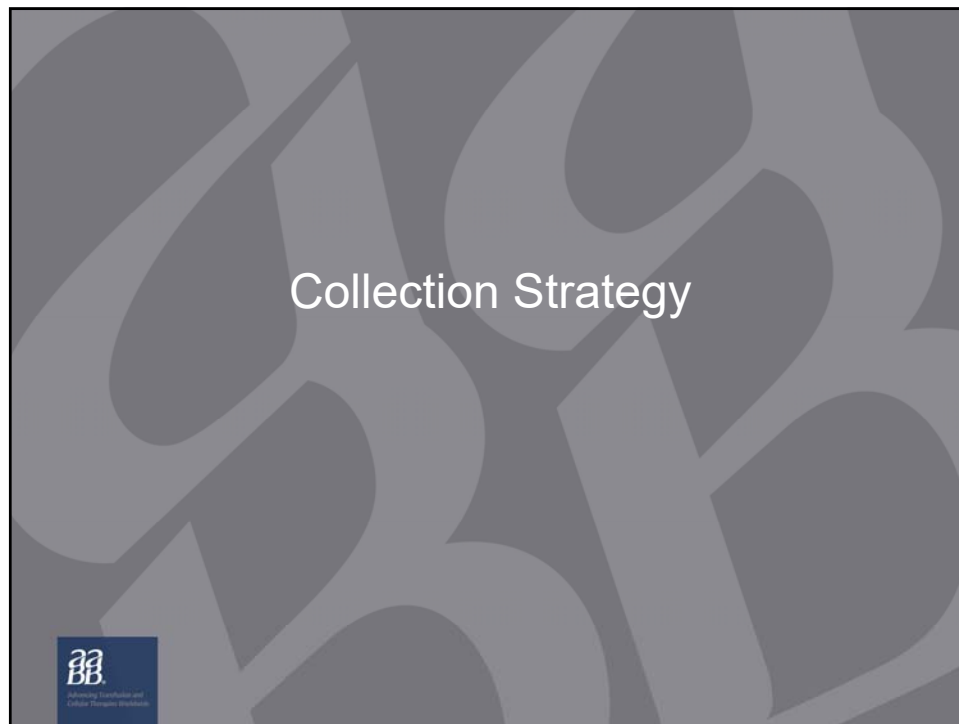
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Factors to Consider When Selecting a Fixed Site

- Demographics of the area
- Exposure
- Traffic to the area
- Competition in the area
- Proximity to other fixed sites
- What products to collect
- Proximity to manufacturing facility
- Costs




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Collect To Need

- Determine the needs of local customers and collect according to need
- Does not work well in an enterprise system where resources are shared within the enterprise – must collect to resource share with others in the enterprise
- Determine what products you need for distribution
 - SDPs
 - Random platelets
 - Red cells
 - Plasma
 - Cryo



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Follow a Model To Determine Collection Needs – Information Needed

- Daily distribution needs for each product
- Outdates at customer sites
- Returns from customers if allowed
- Seasonality of collections
- Imports
- Exports



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Maintaining An Adequate Supply



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Factors To Consider

- Number of customers
- Par levels of those customers for various products
- Transfusion patterns of customers
- Ordering patterns of customers
- Services offered by customers
- Outdate rates of customers
- Availability of blood and blood products, particularly around holidays
- Outside sources for meeting demand
- Is the customer associated with an academic facility?



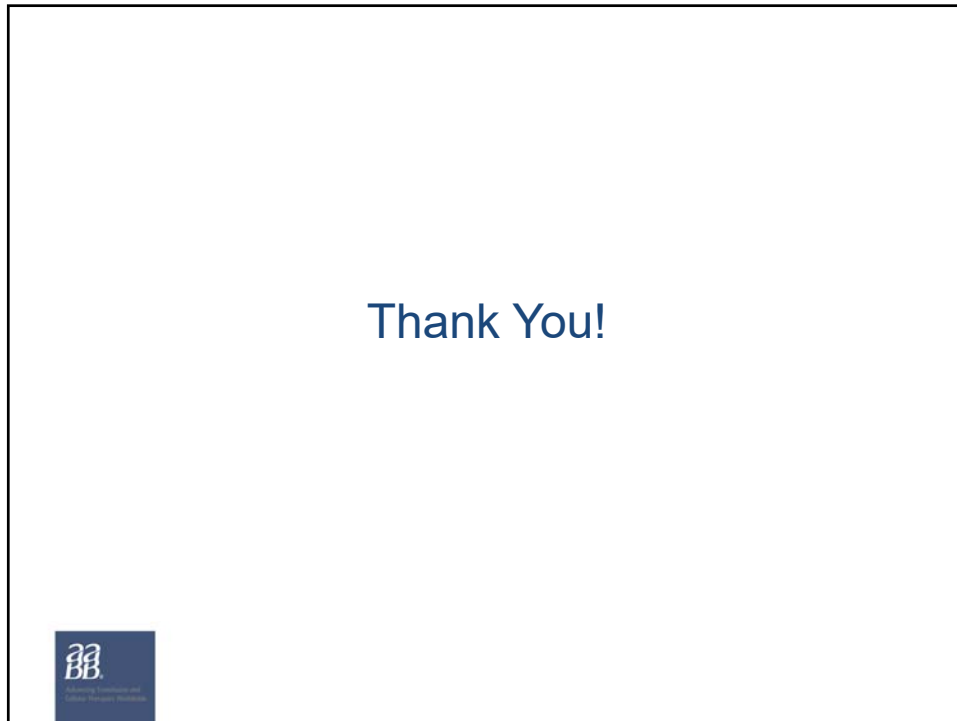
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Tools To Assist

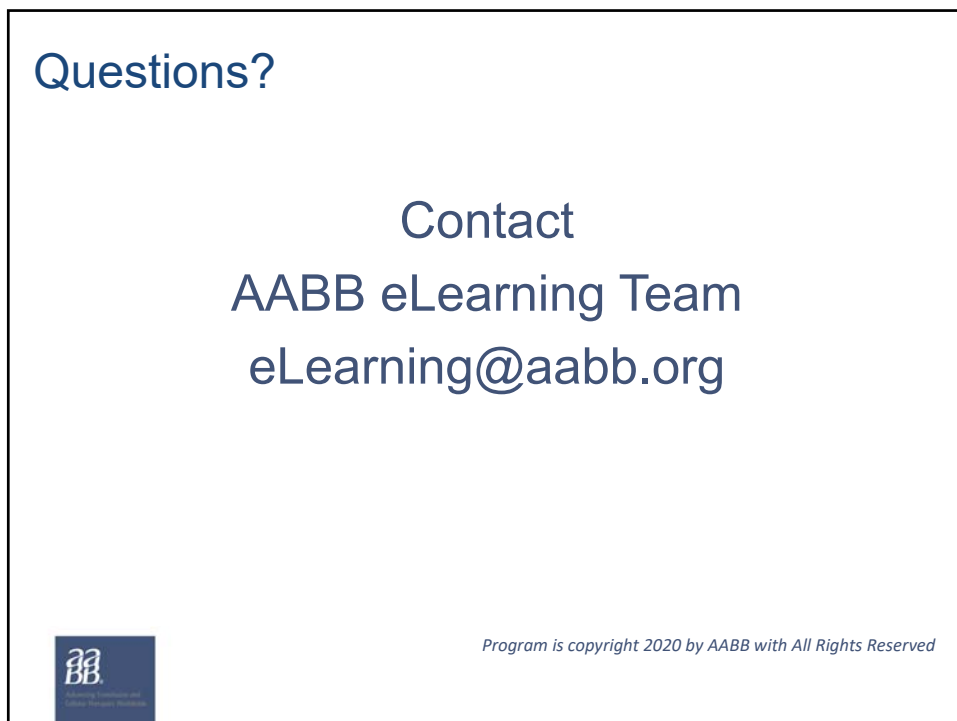
- Data
 - Distribution
 - Orders
 - Outdates
- Models
- Huddles
- Customer Reviews



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